Under section 4.3 in the list of questions an IRB might ask in its deliberations is the following: "What is the payment per participant? Are there any other arrangements"
If this simply refers the amount of compenstion to a study subject, I have no problem. However, if this refers to the amount per subject paid to the investigator, SMO, or TMO, I do have an objection. The amount negotiated between the sponsor and investigator, SMO, or TMO is a business matter that should not be the business of the IRB. Clinical Trial Agreements include study budgets and are contractual agreements between the sponsor and the research entity (investigator, SMO, or TMO). The research entity must negotiate with other parties, oftentimes the institution itself, for payment amounts for certain services or procedures performed relative to the study. If this information is reported to the IRB, it would put the research entity in an unfair and vulnerable negotiating position. This is not the IRB's business. As long as the IRB is assured that sponsor's payments are not influenced or dependent on certain outcomes should be sufficient for the IRB to assure that financial considerations are not influencing study results.
Also, oftentimes, budgets are revised during the course of a study for reasons such as recognition unanticipated expenses. Requiring an investigator to report every change in a study budget is unnecessarily burdensome to both the investigator and the IRB.
Finally, I would like to propose a change in the method of reporting financial conflicts. Currently, every Principal Investigator and subinvesigator is required to complete a financial conflict of interest form for each study and sponsor. This process is very burdensome and causes delays in the start of studies. It also does not assure that an investigator does not develop a conflict during the course of a study. For example, a day trader could be in and out of the stock of a company several times during the course of a study. The current process does not assure that an investigator remains free of a conflict throughout a study.
The Form FDA 15712 provides a "snapshot" of pertinent information relative to a clinical trial. It is an appropriate vehicle for reporting conflicts of interest. I propose adding a section as follows:
"Do you or any of your subinvestigators have a financial conflict of interest relative to this study according to (cite regulation)? No, Yes. If yes, attach an explanation."
The reporting of subsequent development of a financial conflict during the course of a study could be treated in a manner similar to that for reporting SAEs. If the PI or a subinvestigator develops a financial conflict during the course of the study, it should be reported to the sponsor and IRB.

Thank you for the opportunity to comment.
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